The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

London, 15 January 1998
EMEA/CVMP/037/98

PRESS RELEASE

28th MEETING OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

1. At the twenty-eighth meeting of the Committee for Veterinary Medicinal Products, which took place in London on 13 - 15 January 1998, the Committee re-elected Professor R. Kroker as Chairman and Mr. C. O'Sullivan as Vice-Chairman for a period of three years. A list of CVMP Members is included in Annex.

	Opinions delivered since 1.1.1995	Applications under evaluation	Applications anticipated within the next 4 months
Centralised procedures	8	6	9
MRL procedures*	21	28	9

*Applications submitted to the EMEA after 1.1.1995

CENTRALISED PROCEDURES

2. The Committee adopted an Opinion on a variation for a product authorised under the Centralised Procedure and falling under Part B of the Annex to Council Regulation (EEC) No. 2309/93.

3. The Committee heard an oral explanation from an Applicant with regard to an application under evaluation and falling under Part A of the Annex to Council Regulation (EEC) No. 2309/93.

ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS (MRL)

4. The Committee recommended that 1 new substance be included in Annex I to Council Regulation (EEC) No. 2377/90.

5. The Committee concluded the assessment of 2 further applications for new substances after consideration of the consolidated response to the list of questions. The Committee could not recommend the inclusion of these substances in any of the Annexes to Council Regulation (EEC) No. 2377/90 due to outstanding questions which could not be addressed satisfactorily with the data provided by the Applicant.

6. The Committee recommended that 1 old substance with previously provisional MRLs be included in Annex I and 3 old substances be included in Annex II to Council Regulation (EEC) No. 2377/90.

7. The Committee also adopted status reports and lists of questions for 2 old substances.

8. A Rapporteur was appointed for the extension of an existing MRL for 1 substance.

GUIDELINES AND SOPs

9. The Committee adopted an EMEA SOP on Appeal and Provision of Explanations in Support of Objections to CVMP Recommendations on the Establishment of MRLs (EMEA/CVMP/158/97 –FINAL).
10. The Committee adopted a CVMP Note for Guidance on the Establishment of MRLs for *salmonidae* and other fin fish (EMEA/CVMP/153b/97 - FINAL) following the close of the consultation period.

Both documents come into effect immediately.

11. The Committee adopted a revised Note for Guidance on Excipients in Veterinary Medicinal Products (EMEA/CVMP/004/98 – Consultation) for release for 3 months consultation.

ANY OTHER BUSINESS

12. The next meeting of the Committee will be held on 10 – 12 February 1998.

Annex

List of CVMP Members for 1998-2000

Chairman :	KROKER Reinhard		
Belgium	PASTORET Paul-Pierre FALIZE Françoise	Deutschland :	EGLIT Sabine MOOS Manfred
Osterreich :	DICHTL Johannes OBERMAYR Eugen	Ellas :	HIMONAS, Christos MALEMIS, Ioannis
Portugal :	PRATAS Magarida SINOGAS Carlos	France :	BOISSEAU Jacques MOULIN Gérard
España:	CORBALAN, Luis SOBRINO, Odon	Ireland :	BEECHINOR J. Gabriel O'SULLIVAN Cyril (Vice-Chairman)
Suomi :	KAARTINEN Liisa PYÖRÄLÄ, Satu	Italia :	CONTI Gabriella MACRI Agostino
Sverige :	LUTHMAN Jan WENNBERG Annika	Nederland :	LENSING Herman HEKMAN, Peter
United Kingdom :	RUTTER J.Michael O'BRIEN John	Luxembourg:	WIRTOR, Marc HUBERTY, Albert
Danmark :	HARTMANN FRIES, Helle FRIIS Christian		

Maximum Residue Limits for New Substances adopted by the Community since 1.1.1995
(Status: January 1998)

Substance a) INN	**Therapeutic area** a) Target species	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Sent to Commission b) Date of the regulation c) OJ No.
a) Difloxacin	a) Chicken, turkeys	a) 16.05.95 b) 15.12.95 c) 134 days d) 49 days	a) 13.02.96 b) 08.07.96 c) OJ No. L 170 of 09.07.96
a) Ketoprofen (extension)	a) Porcine	a) 15.05.95 b) 22.03.96 c) 85 days d) 217 days	a) 25.04.96 b) 06.09.96 c) OJ No. L 226 of 07.09.96
a) Diclazuril	a) Ovine	a) 12.12.95 b) 24.04.96 c) 104 days d) 0	a) 24.05.96 b) 21.10.96 c) OJ No. L 269 of 22.10.96
a) Eprinomectin	a) Bovine	a) 22.02.96 b) 25.06.96 c) 108 days d) 0	a) 26.07.96 b) 08.01.97 c) OJ No. L 5 of 09.01.97
a) Doramectin (modification)	a) Bovine	a) 14.05.96 b) 24.07.96 c) 70 days d) 0	a) 23.08.96 b) 14.02.97 c) OJ No. L 45 of 15.02.97
a) Praziquantel	a) Ovine	a) 03.08.95 b) 18.09.96 c) 187 days d) 152 days	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Moxidectin (modification)	a) Bovine and Ovine	a) 12.06.96 b) 18.09.96 c) 97 days d) 0	a) 16.10.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Difloxacin (modification)	a) Chicken, Turkeys	a) 10.07.96 b) 23.10.96 c) 104 days d) 0	a) 19.11.96 b) 25.04.97 c) OJ No. L 110 of 26.04.97
a) Ivermectin (extension)	a) Deer	a) 20.08.96 b) 11.12.96 c) 86 days d) 0	a) 09.01.97 b) 23.04.97 c) OJ No. L 106 of 24.04.97
a) Amitraz (extension)	a) Bees	a) 18.10.96 b) 12.02.97 c) 115 days d) 0	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97
a) Doramectin (extension)	a) Swine and Ovine	a) 10.06.96 b) 12.02.97 c) 118 days d) 127 days	a) 12.03.97 b) 24.09.97 c) OJ No. L 263 of 25.09.97

Maximum Residue Limits for Old Substances adopted by the CVMP and the Community
(Status: January 1998)

TOTAL 318			
Annex I	Annex II	Annex III	Annex IV
48	229	30	11
Published in the Official Journal of the European Communities: 270			

Veterinary Medicinal Products which have been granted a Community marketing authorisation under the centralised procedure
(Status: January 1998)

Product a) Brandname b) INN c) List A/B	**Company** a) Name b) Origin	**Therapeutic area** a) Target species b) Indication	**Presentation** a) Form b) Dosage c) No. of presentations	**EMEA/CVMP** a) Validation b) Opinion c) Active time d) Clockstop	**Commission** a) Opinion received b) Decision c) Notification d) OJ No.
a) Nobi-vac-Porcoli b) Inactivated vaccine c) List A	a) Intervet International b) NL	a) Piglets b) Neonatal colibacillosis	a) Solution for injection b) Multidose c) 2	a) 01.01.95 b) 27.07.95 c) 107 days d) 94 days	a) 24.08.95 b) 29.02.96 c) 04.03.96 d) OJ No. C/96 of 29.03.96
a) Pentofel b) Vaccine c) List A	a) Fort Dodge Laboratories b) IRL	a) Cats b) Rhinotracheitis	a) Solution for injection b) Monodose c) 3	a) 16.06.95 b) 18.09.96 c) 208 days d) 235 days	a) 17.10.96 b) 05.02.97 c) 06.02.97 d) OJ No. C/63 of 28.02.97

1998 MEETINGS OF THE CVMP AND OF ITS WORKING PARTIES

CVMP

10-12	February	1998
10-12	March	1998
7-8	April	1998
5-7	May	1998
9-11	June	1998
7-9	July	1998
8-10	September	1998
13-15	October	1998
10-12	November	1998
8-10	December	1998

Residues WP

21-23	January	1998
4-6	March	1998
22-24	April	1998
3-5	June	1998
15-17	July	1998
2-4	September	1998
7-9	October	1998
25-27	November	1998

CPMP/CVMP Quality WP

3-5	June	1998
7-9	October	1998

IVMPs WP

9	February	1998
8	June	1998
12	October	1998
7	December	1998

Pharmacovigilance WP

9	March	1998
12	June	1998
11	September	1998
7	December	1998

Efficacy WP

9	February	1998
6	April	1998
8	June	1998
7	September	1998